12. (Amended) A supplement for enhancing immune response of a dog or cat, said supplement comprising, on a dry matter basis, from about 0.001 to about 2% by weight lutein.

REMARKS

In the first Office Action, the Examiner rejected claims 1-12 and 14 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,133,323 to Hayek. Hayek teaches a diet for companion animals containing β-carotene to enhance immune response. The Examiner acknowledges that Hayek does not teach the use of lutein for enhancing immune response, but has taken the position that since Hayek discloses that carotenoids including lutein are known to modulate the immune system, it would have been obvious to use lutein to enhance the immune response of companion animals. However, there is no teaching or suggestion in Hayek of administering the claimed dosage of lutein, nor is there any teaching or suggestion for administering lutein for the purpose of increasing lutein concentration in the blood, increasing immunoglobulin concentration, or increasing lymphocyte cells in a companion animal as recited in claims 1 and 9-11. At best. The Examiner has posited an "obvious to try standard for obviousness, which standard is improper as a basis for rejection. Applicants respectfully submit that this rejection is improper and should be withdrawn.

Claims 1-12 and 14 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Independent claims 1 and 12 have now been amended as suggested by the Examiner. Claims 1-12 and 14 are believed to be in compliance with §112.

Claims 1-12 and 14 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Jyonouchi et al. (CA Abstract, AN 1994:321921) in view of Anon (Biobusiness Abstract AN 97:19144), Ito et al., U.S. Patent No. 5,937,790 and Krinsky (Medline Abstract, AN 91090021), further in view of the CRC Handbook of Toxicology. Ito et al. (newly cited) teach a method of reducing stress in animals including dogs, cats, fish, cattle and pigs which discloses administering an anti-stress agent which may optionally include an antioxidant such as lutein.

However, there is no teaching or suggestion in Ito et al. that antioxidants, specifically, lutein may be used to enhance immune response. Rather, Ito et al. teach the optional use of antioxidants to enhance the anti-stress agent's effect of suppressing increased stress proteins. See col. 6, lines 42-48.

Krinsky (newly cited) teaches that carotenoids may help reduce the risk of cancer and provide immunoenhancement in humans based on results of experiments performed on animal systems. There is no teaching in Krinsky that the administration of carotenoids, specifically lutein, enhances the immune response of dogs or cats.

The Examiner asserts that one skilled in the art would have been motivated to feed a supplement containing lutein to a dog or cat based on the teachings of the prior art references. However, there is no factual basis for the Examiner's conclusions.

Jyonouchi et al. teach the effects of administration of lutein to mice, not dogs or cats. Further, Jyonouchi's results are based on immune enhancement in response to specific T-dependent antigens, and Jyonouchi's results suggest that carotenoids may be beneficial for *older* animals. Nothing in Jyonouchi suggests that administration of lutein to cats or dogs would be beneficial.

Anon teach a dietary supplement containing lutein which is indicated to be associated with *eye health*. Ito et al. teach the optional use of an antioxidant such as lutein to suppress increased stress proteins in animals, not to enhance immune response. Krinsky teaches that carotenoids may help reduce the risk of cancer and provide immunoenhancement in *humans*. None of these references relate to enhancing immune response in dogs or cats.

The CRC Handbook of Toxicology includes a general statement that animals may be used to study the diseases of humans. However, there is no teaching or suggestion in the handbook that the administration of lutein to one animal would serve as a predictable model for all animals.

None of the references, taken alone or in combination, suggest to one skilled in the art that the administration of lutein in the claimed amounts to a dog or cat would enhance immune

response, increase lutein and immunoglobulin concentration in the blood, or increase lymphocyte cell concentration in the blood as recited in independent claims 1 and 9-11.

Claims 1-12 and 14 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al. While the Examiner admits that Ito et al. do not specifically teach the use of lutein, he considers it to be an obvious choice from a selection of "equally suitable" materials. Again, the Examiner has provided no factual basis for his conclusions. There is no teaching or suggestion in Ito that lutein may be used to enhance immune response. Ito et al. are concerned with providing an anti-stress agent such as L-ascorbic acid-2-phosphoric acid which may ***optionally*** contain an antioxidant to provide enhanced anti-stress effects. There is nothing in Ito et al. which would suggest to one skilled in the art that the selection of lutein or lutein alone may be used to enhance immune response in dogs or cats.

For all of the above reasons, applicant submits that claims 1-12 and 14 are patentable over the cited references. Early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,

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APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) A process for enhancing immune response of a [companion animal consisting of a] dog or cat, said process comprising the step of feeding said animal a diet containing from about 1 to about 50 mg/day of lutein for a time sufficient for said lutein to be absorbed by said animal.

12. (Amended) A supplement for enhancing immune response of a [companion animal consisting of a] dog or cat, said supplement comprising, on a dry matter basis, from about 0.001 to about 2% by weight lutein.